Patient Warming Mattress
Model U10X
User Manual

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DEVICE DESCRIPTION

The Hot Dog Patient Warming Mattress is a component of the Hot Dog Patient Warming System and should only be used with Hot Dog Controller Model WC5X. These instructions apply to Warming Mattress Model U10X.

The Warming Mattress provides a surface area for under-body patient warming at a specified and uniform temperature. An internal temperature sensor provides output to the Hot Dog Controller to maintain the set temperature. The Warming Mattress has a built-in pressure relief pad and is water and solvent resistant. All seams are fully sealed to allow for easy cleaning and disinfection.

INDICATIONS FOR USE

The Hot Dog Patient Warming Mattress is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming Mattress should be used in circumstances in which patients could become cold. In addition, the mattress is designed to provide pressure relief. The Hot Dog Patient Warming System is intended primarily for use in hospitals and surgical centers including without limitation operating, recovery, and emergency rooms and on medical/surgical floors.

CONTRAINDICATIONS

- DO NOT warm patients during aortic cross-clamping; thermal injury may result.
- DO NOT warm patients with ischemic or non-perfused limbs; thermal injury may result.
- DO NOT warm patients receiving transdermal medication; increased drug delivery may occur.
- DO NOT use the Warming Mattress on patients weighing over 300 lbs (136 kg).
- DO NOT use the Warming Mattress with other under-patient thermal management systems.

WARNINGS

- EXPLOSION HAZARD – DO NOT use the Warming Mattress in the presence of flammable anesthetics or highly oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Caution should be taken when using electric warming devices with HF surgical instruments or endocardial catheters in respect to potential equalization.
- Inspect the Warming Mattress prior to use for signs of damage or excessive wear such as cuts, holes or loose electrical connections. If signs of wear are evident, do not use the Warming Mattress until it is inspected by technical staff.
- DO NOT continue to use the Warming Mattress if the Hot Dog Controller over temperature indicator and/or alarm continues to sound after reset.
- The Warming Mattress is not sterile. Take appropriate precautions, as necessary, to protect the sterile field.
- Use only with Hot Dog Controller Model WC5X.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

PRECAUTIONS

- Use under the direct supervision of a clinician.
- Monitor the patient's vital signs regularly during warming according to institutional protocol. If vital sign instability occurs, notify the clinician.
- Care should be taken when using multiple warming methods.
- Ensure that the Warming Mattress is securely fastened to the table.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; ensure that surgical prep solution instructions for use are followed.
- The use of gel pads between the Warming Mattress and the patient is not recommended; gel pads may cause a loss of warming performance.
- Always use a patient barrier between the patient and the Warming Mattress.
- Position the patient on flat Warming Mattress.
- Care should be taken to alleviate or remove the risk of heating skin under pressurized bony prominences.
- Care should be taken to place the patient's body in contact with the labeled sensor on the Warming Mattress.
- DO NOT use operating table clamps or similar devices on the Warming Mattress as they may cause damage to the product and result in loss of the heating function and/or localized heat build-up in the damaged area.
- DO NOT place the Warming Mattress over a table joint that will move during surgery.
- DO NOT use on OR tables wider than 20 inches (50.8 cm).
- DO NOT use the Warming Mattress as a stand-alone patient pressure relief system.
- DO NOT place any hard objects (e.g., mattress cables, EKG cables, hard cautery return pads, patient fluid lines, etc.) between the Warming Mattress and the patient's body.
- DO NOT fold or wrinkle the Warming Mattress during use as localized heat build-up may occur in the overlapped area.
- DO NOT use the Warming Mattress when pressure injury is a concern.
- DO NOT X-ray or MRI through the white labeling or edges of the Warming Mattress.
- DO NOT allow patient fluid lines to be placed between the Warming Mattress and Warming Blanket or other warming equipment.
- DO NOT position the patient's head directly on the Warming Mattress.
- DO NOT allow the heated side of a Hot Dog Warming Blanket to come in continuous contact with the Warming Mattress when both devices are on.

INSTRUCTIONS FOR USE

Contents

The following components are included in the Hot Dog Patient Warming Mattress package:

1 -- Warming Mattress

1 -- Mattress Cable (P/N A112)

The following supplies are not provided but are required for use with the Warming Mattress:

1 -- Patient barrier (e.g., thin cotton sheet)

General Instructions

1. Inspect the surface of the Warming Mattress for damage (e.g., cuts, tears, creases). Do not use the Warming Mattress if it is damaged.
2. Place the Warming Mattress on the padded operating table.

Note: Ensure "THIS SIDE UP" labeling faces up.

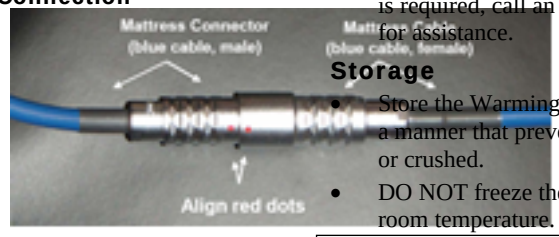
3. Attach the Warming Mattress straps to the operating table.

Warning: Ensure that the straps on each side of the Warming Mattress are firmly secure. If the straps are not secure, the mattress can slide off the table, resulting in patient injury.

4. Place a patient barrier over the entire surface of the Warming Mattress.
5. Insert the female end of the blue Mattress Cable into the Mattress Connector (**Figure 1**).

Note: Do not force the connector into the socket. Align the red dots on each connector and gently push the connectors together. You will feel a click when the connectors engage.

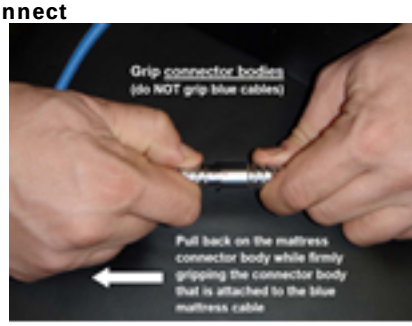
Figure 1: Cable Connection



6. Insert the male end of the blue Mattress Cable into the blue port on the Hot Dog Controller.
7. Turn the Hot Dog Controller on and select the desired temperature setting to begin warming. Allow 5 minutes for the Warming Mattress to reach set point. (Refer to the Hot Dog Controller User Manual.)
8. If the Hot Dog Controller alarm sounds when the Warming Mattress is connected, do not use the Warming Mattress. (Refer to the "Alarms" section.)
9. When use of the Warming Mattress is complete, clean as necessary. (Refer to the "Care and Maintenance" section.)
10. To disconnect the Mattress Cable, grip the connector bodies and pull them apart (**Figure 2**).

Note: Do not pull on the cables or attempt to rotate or unscrew the connectors. Bending or twisting the cables or connectors may result in damage to the wires or the connector pins.

Figure 2: Cable Disconnect


Grip connector bodies
(do NOT grip blue cables)
Pull back on the mattress connector body while firmly gripping the connector body that is attached to the blue mattress cable

CARE AND MAINTENANCE

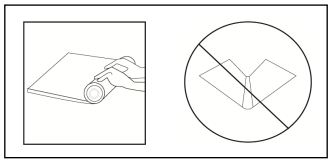
- DO NOT launder or sterilize as this may damage the Warming Mattress.
- DO NOT immerse the Warming Mattress in liquids.
- DO NOT use high-level disinfectants (e.g., gluteraldehyde, peracetic acid) to clean the Warming Mattress.
- DO NOT spray cleaning solutions into the electrical connector.
- DO NOT use cleaning or disinfection methods different from those recommended in the User Manual without first checking with an authorized service representative to ensure that the proposed methods will not damage the equipment.
- DO NOT use the Warming Mattress if it shows signs of damage or excessive wear such as cuts, holes or loose electrical connectors. Technical staff should inspect the Warming Mattress to determine if it is safe for use.
- DO NOT disassemble the Warming Mattress; the product contains no user serviceable parts. If service is required, call an authorized service representative for assistance.

Storage

- Store the Warming Mattress in a dry place and in a manner that prevents the product from being cut or crushed.
- DO NOT freeze the Warming Mattress; store at room temperature.

Note: If the Warming Mattress has been exposed to freezing temperatures, do not bend or roll the product as this may result in cracks to the pressure relief pad. Allow the product to reach room temperature prior to handling.

- DO NOT store any other objects on top of the Warming Mattress.
- DO NOT fold or sharply bend the Warming Mattress; the recommended storage configuration is flat (preferred) or rolled.



Cleaning—General

Clean the Warming Mattress between each patient use and anytime it appears soiled. Wipe the mattress with a damp soapy cloth and disinfect following standard hospital protocol. In general, alcohol-based disinfectants are easiest to use since they are fast acting and can be either sprayed or wiped on the mattress. Other cleaners that are compatible with the outer surface of the mattress include sodium hypochlorite (diluted bleach), phenolic germicidal detergent, and quaternary ammonium detergent. Iodine containing cleaners may cause discoloration of the surface material and are therefore NOT recommended for routine cleaning. Dry thoroughly before use.

Caution: DO NOT place the Warming Mattress in an autoclave, sterilizer, automatic washer-disinfector or any other high temperature system as this may damage the product.

Cleaning & Disinfection Steps

The cleaning steps below are general recommendations and are not meant to replace hospital-specific cleaning protocols.

1. DO NOT allow cleaning fluids to get into the electrical connector.
2. If visible soiling is present, remove before applying a disinfectant. Scrub the affected area with detergent, using a soft brush or sponge to remove organic matter. Rinse the surface of the mattress using a dampened cloth. Do not immerse the mattress in liquids.
3. Apply a low or intermediate level disinfectant to the entire mattress by spraying or wiping. Follow the disinfectant manufacturer's application instructions to ensure disinfection.
4. Dry thoroughly before use.

ALARMS

If the Warming Mattress temperature exceeds one degree above set point or other fault conditions exist, an audible alarm sounds and the Controller Alarm Light illuminates red for the port that is alarming. The Controller will automatically discontinue power to the Warming Mattress. When the operating temperature is regained, the alarm will shut off and normal function will be restored. If the Alarm Light illuminates steadily and the alarm continues to sound, turn the Controller Mains Power Switch to the OFF position and disconnect the Warming Mattress from the Controller. If the Controller senses an over current, the audible alarm will sound and all alarm lights will illuminate. Power will be lifted from all ports and the Controller will need to be turned off to reset. If all Alarm Lights illuminate after resetting the Controller, discontinue use of the Warming Mattress.

DEFINITION OF SYMBOLS

	Attention, consult accompanying documents.		Latex Free		BF Patient Applied Part according to IEC60601-1.
	Serial Number		Reference Number		Not Sterile
	Manufacture Date		Use only with Hot Dog Patient Warming Controller.		Store as directed in instructions for use.
	Protect from sharp objects. Discontinue use if product is cut or damaged.		Keep Dry		Conforms to European Medical Device Directive 93/42/EEC.
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Return to Authorized Representative
	Temperature Sensor		This Side Up		

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